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In The

Supreme Court of the United States

FESTO CORPORATION,

Petitioner,

v.

SHOKETSU KINZOKU KOGYO KABUSHIKI CO., LTD., A/K/A SMC CORPORATION and SMC PNEUMATICS, INC.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeal For The Federal Circuit

BRIEF OF AMICUS CURIAE CELLTECH GROUP PLC. IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

Page

STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT..... 2

ARGUMENT 4

I. THE *FESTO* DECISION LEAVES CELLTECH A "POWERLESS LICENSOR"..... 4

A. The Complete Bar Rule of *Festo* Has Especially Severe Consequences to Biotechnology Patentees..... 4

B. *Festo* Allows Celltech's Licensee to Pirate Celltech's Invention with Impunity..... 5

II. THE *FESTO* DECISION SHOULD NOT BE APPLIED RETROACTIVELY 8

CONCLUSION 9

TABLE OF AUTHORITIES

Page

CASES

Amgen, Inc. v. Hoechst Marion Roussel, 126 F.Supp. 2d 69 (D. Mass. 2001) 5

Bio-Technology Gen. Corp. v. Genentech, Inc., 80 F.3d 1553 (Fed. Cir. 1996)..... 4

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558 (Fed. Cir. 2000)..... *passim*

Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997) 8

STATEMENT OF INTEREST

Celltech Group plc. ("Celltech") is one of the largest biopharmaceutical companies in Europe.[1] Celltech focuses on drug discovery and development, novel gene target identification and therapeutic antibody technologies. Celltech has several patented technologies including patents relating to antibody engineering and antibody production. By licensing its patents, Celltech generates a royalty stream to fund its further research and development.

Celltech is currently in a dispute before an English court concerning the question of whether a product made by a licensee falls within the scope of one of Celltech's important United States patents relating to humanized antibodies. In that dispute, the licensee has alleged that, *inter alia*, because of the decision of the Court of Appeals for the Federal Circuit in *Festo*, it is not obliged to pay royalties on a virtually identical humanized antibody. That case therefore emphasized that the fears expressed by Judge Michel in his opinion are well founded. Celltech made an important invention, but, as is virtually inevitable in the case of biotechnology patents, amended the originally-filed claims during the course of prosecution in

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[1] Written consent to the filing of this brief has been obtained from the parties and is lodged herewith. Celltech Chiroscience Ltd., the entity listed in the letters of consent, is a subsidiary of Celltech Group plc. Counsel for a party did not author this brief in whole or in part. No person or entity other than the *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

certain respects. Celltech's licensee is using those amendments to escape the payment of royalties in a manner that illustrates the special difficulties to which the majority decision in *Festo* will give rise in the context of biotechnology cases, should this Court uphold the decision.

SUMMARY OF ARGUMENT

In his concurring in part and dissenting in part opinion in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558, 617 (Fed. Cir. 2000) (*en banc*), Judge Michel identified the biotechnology field, in particular, as being one which was likely to be harmed by the majority's new complete bar rule. He noted that "[c]ompletely barring resort to the doctrine of equivalents for amended claim limitations may drastically limit the scope of protection for biotechnology patents, such as those claiming a protein molecule." *Id.* Celltech submits this *amicus curiae* brief to provide the Court with a "real world" example of how a licensee who entered into a pre-*Festo* license can use *Festo*'s complete bar to avoid paying very substantial royalties.

The complete bar rule provides copyists with a fail-safe method to avoid liability for infringement. *Id.* at 616. First, copyists can read the prosecution history to identify amendments made for patentability reasons. Second, copyists can then copy all unamended limitations exactly, but substitute any known interchangeable structure, matter or step for any limitation that has been amended. Regardless of how unimportant or insubstantial, a change

to just one amended limitation will be sufficient for the copyist to avoid liability under the complete bar rule.

Biotechnology patents with limitations that have been amended during prosecution, especially those claiming a protein or nucleic acid molecule, will be particularly susceptible to attack by copyists. Slight modifications to biotechnology inventions, such as a change of one amino acid or nucleotide, are routine and often have no substantive impact on the molecule, but can defeat literal infringement. If limitations in the patent's claims have been amended during prosecution for a reason related to patentability, the patentee will be completely barred from protecting their innovations against a determined copyist. A competitor seeking to make, use, or sell a patented protein, or a similar biotechnology invention, where the underlying patent contains an amended claim limitation will only have to make a known interchangeable amino acid substitution at one position in a protein to avoid infringement, literal or otherwise.

The complete bar rule directly impacts untold numbers of licensing agreements that are predicated on the assumption that patent claims with an amended limitation are still entitled to a range of equivalents. *Festo*, 234 F.3d at 619 (Michel, J., dissenting in part). Licensees and others will be tempted to exploit the complete bar rule by using the two-step method for liability-free copying discussed above. *Id.* By making a routine substitution of a known interchangeable element in an amended claim limitation, but exactly copying every other limitation in the patent, a licensee can then correctly assert that it is no longer practicing the patented invention under the

license and refuse to pay royalties. *Id.* Under the complete bar rule, the licensor would be powerless to enforce the license because the patent claims do not literally cover the routinely-modified product, and the patentee/licensor would be barred from asserting infringement under the doctrine of equivalents.

As a victim of such a would-be copyist and exploiting licensee, Celltech provides the Court with a "real-world" example of the severe impact the complete bar rule could inflict on patentees and licensors.

ARGUMENT

I. THE *FESTO* DECISION LEAVES CELLTECH A "POWERLESS LICENSOR"

A. The Complete Bar Rule of *Festo* Has Especially Severe Consequences to Biotechnology Patentees

The *Festo* decision was made in the context of considering a mechanical invention. Biotechnology inventions have special features. Biotechnology is founded on genetic sequences embodied in nucleic acids and proteins. It is a field in which it is particularly difficult to write claims that strike the right balance between specificity and sufficient comprehensiveness to catch copyists.

This is principally because, once an inventor has discovered a relevant genetic sequence, it is known that small modifications can usually be made to that sequence without significantly affecting its function. *See, e.g., Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1556

(Fed. Cir. 1996) (accused infringer copied the patented human growth hormone protein but deleted one amino acid); *Amgen, Inc. v. Hoechst Marion Roussel*, 126 F.Supp. 2d 69, 132-133 (D. Mass. 2001) (accused infringer copied the patented erythropoietin protein but deleted one amino acid). Biotechnology inventions and the claims relating to them can be thought of as maps giving the "co-ordinates" of a portion of the genetic terrain where a particular beneficial characteristic can be found. There will almost always be a periphery of terrain around the given co-ordinates where those characteristics are also to be found.

Amendments to such patents during prosecution are very common – if not virtually universal – as are statements describing the prior art and how it differs from the claimed invention. *See Festo*, 234 F.3d at 638 (Newman, J., dissenting in part) (stating that very few patents issue with claims as originally filed). If, as soon as the patentee differentiates its "co-ordinates" from those of the remote co-ordinates of prior art, there is a risk of an automatic and complete estoppel, it will effectively be impossible to give fair protection to the patentee.

B. *Festo* Allows Celltech's Licensee to Pirate Celltech's Invention with Impunity

Celltech owns U.S. Patent No. 5,859,205, relating to "humanized" antibodies. Antibodies are protein molecules, made from chains of amino acids that have the ability to bind to a wide variety of biologically relevant molecules, including proteins found in specific bacteria,

viruses, and tumor cells. Antibodies are frequently generated from a non-human source such as a mouse. When non-human antibodies are administered to patients, the patient's immune system normally recognizes the antibody as foreign, which can impede the antibody's effectiveness and produce undesirable side effects. Antibody humanization seeks to minimize or avoid such responses by creating antibodies that are more "human" by replacing non-essential parts of the mouse-derived protein with the equivalent human-derived protein sequence. The humanized antibody retains its ability to bind to a specific protein, but is less likely to be rejected by the patient's immune system.

Celltech licensed its patented technology relating to humanized antibodies to a U.S. biopharmaceutical company, MedImmune, Inc. ("MedImmune"). The license provided that MedImmune was to pay royalties if the manufacture or sale of its products fell within the scope of Celltech's U.S. or foreign patents. After entering into the licensing agreement, MedImmune began marketing a humanized antibody product that was virtually identical to Celltech's patented technology.

The only difference between the licensee's product and Celltech's technology is that one amino acid at one location in the antibody protein sequence is different. The whole antibody consists of two paired sequences consisting of approximately 1,320 amino acids. The substituted amino acid in the licensee's product is threonine, which is a known interchangeable substitute for the amino acid in Celltech's technology, serine. The use of serine or threonine at this location in the antibody protein sequence has

no significant impact on the antibody's ability to bind with the biological molecule of interest.

Because Celltech's licensee contends that its product is not covered by Celltech's U.S. Patent and therefore no royalties are due, Celltech filed suit against its licensee in the Patents Court of the Chancery Division of the High Court of Justice for England and Wales in October 2000. The action alleged that the licensee's product fell within the scope of the claims of the U.S. patent. The Federal Circuit issued its *Festo* decision shortly thereafter, and Celltech's licensee, in its defense, asserted that prosecution history estoppel provided it with a complete defense to Celltech's action, basing its argument, *inter alia*, on the *Festo* decision.

Due to the single, although recognizably interchangeable, amino acid substitution between Celltech's technology and its licensee's product, Celltech cannot assert literal infringement. It must therefore rely on the doctrine of equivalents to establish infringement, and in turn the basis for the obligation to pay royalties. However, as is almost invariable in the course of prosecuting biotechnology patents, Celltech amended its claims during prosecution of its U.S. patent. Its licensee has argued that the amendments were made for patentability purposes and, therefore, completely bar Celltech from asserting any scope of equivalents under the majority's decision in *Festo*. The U.K. Patents Court Judge recently stayed the English action until this Court rules on its review of the *Festo* decision.

For the reasons explained above, Celltech agrees with the Petitioner that the Federal Circuit's new complete bar

rule runs contrary to the realities of established patent prosecution practice and will unfairly impact the biotechnology industry.

II. THE *FESTO* DECISION SHOULD NOT BE APPLIED RETROACTIVELY

Celltech submits that even if the Court confirms the majority decision of the Federal Circuit in *Festo*, it should not do so in a way that affects vested rights. Even the *Festo* majority recognized that its decision represented a change in the law. *Festo*, 234 F.3d at 571. The unfairness of this type of change was noted by a member of this Court, who commented that a change in the law of prosecution history estoppel would "unfairly discount the expectations of a patentee who had no notice at the time of patent prosecution that such [a rule] would apply." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 41 (1997) (Ginsburg, J., concurring).

Celltech's situation will be a common occurrence if *Festo* stands as written. After *Festo*, licensees will have a strong economic incentive to use the "*Festo* roadmap" to avoid paying royalties. Licensees, which benefit from the technological innovations of their licensors, are well-placed to determine what insubstantial changes can be made to patented inventions – especially when it comes to biotechnology inventions – without affecting the resulting product. Thus, if *Festo* is applied retroactively, many licensors will be deprived of their expected

royalties without any notice that the patent they prosecuted or the license they negotiated would be valueless.

CONCLUSION

The complete bar rule announced in *Festo* has provided would-be copyists, including existing licensees, with potential means to avoid infringement and the payment of royalties. Rather than furthering the public policy of fostering innovation, the majority's decision in *Festo* has had the pernicious effect of encouraging imitation and stifling the advancement of important and significant technologies. This Court should reverse the majority opinion below or limit its application to patents that issue from applications filed after the issuance of the opinion below.

Respectfully submitted,

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